CYCLOTRON FOR SHORT LIVED MEDICAL RADIOISOTOPES (CZR/4/007) G5 New

MODEL PROJECT

CORE FINANCING

YEAR	Experts		Group Activity	Equipment	Fellowships		Scientific Visits		Group Training	Sub-Contracts	Misc. Comp.	TOTAL
	m/d	US $	US $	US $	m/d	US $	m/d	US $	US $	US $	US $	US $
1997	0/27	11,880	0	240,000	9/0	28,350	0/0	0	0	0	0	280,230
1998	1/0	13,950	0	450,000	6/0	19,800	0/0	0	0	0	0	483,750
1999	0/0	0	0	474,000	6/0	20,700	0/0	0	0	0	0	494,700
2000	0/0	0	0	400,000	0/0	0	0/0	0	0	0	0	400,000

First Year Approved: 1997

OBJECTIVES: The major development objective is to improve health care delivery in an area of high national importance, circulatory disorders, while reducing overall diagnosis and management costs. The project's specific aims are to assist in the establishment of a cyclotron facility for the production of short lived radiopharmaceuticals, and to promote their full utilization in medical practice.

BACKGROUND: Approximately 120,000 persons in the Czech Republic die each year, 68,000 (57%) of diseases of the circulatory system, the largest percentage in Europe. Under the present standard assessment (laboratory tests, nuclear and/or non-nuclear exercise testing, cardiac catheterization), about 18,500 cases require surgery. However, Czech hospitals have a capacity of only about 10,000 operations per year, about 5000 percutaneous translumino coronary angioplasty (PTCA) and 5000 by-pass. Furthermore, the present assessment does not adequately appraise the risks or benefits of the surgery, resulting in incorrect treatment and unnecessary operations. Today, almost every country must severely cut the costs of its health care system. One very effective way to improve the quality of health care while reducing costs is the use of positron emission cameras and tomographic (PET) procedures. Ideally, about 70% (20,000) of hospitalized patients in the Czech Republic should be first studied by PET for salvageable myocardium. This approach would reduce the number of cardiac catheterizations and revascularizations. About 6000 PET scans per year are performed in cardiology alone at present. The number should increase to over 20,000 in a few years. The conventional radiopharmaceuticals used during nuclear medicine examinations have reached the limits of their potential and cannot provide further improvements in diagnostic efficiency or health care cost reductions. Furthermore, despite significant advances in the past two decades in morphological imaging, pathological changes often become apparent only after the disease has reached a fairly advanced stage. On the other hand, pathophysiological alterations in organ function or metabolism usually occur and can be detected long before there is visual evidence of structural change. The introduction of PET actively stimulated the development of more effective radiopharmaceuticals and created the possibility of using labelled metabolites and many other carrier molecules which otherwise could not have been labelled. These advances clearly demonstrate the potential of nuclear medicine to monitor subtle changes in metabolism and thus detect the earliest stages of many serious diseases. Owing to its high diagnostic accuracy, nuclear medicine has a positive impact on recovery rates, as well as on health care costs. Results from the clinical application of positron-emitting radiopharmaceuticals in more than 100 PET centres all over the world demonstrate very clearly that positron emitters are a new tool in diagnostics which can substantially increase both the quality and effectiveness of health care.

PROJECT PLAN: The project will assist in the establishment of a national facility for cyclotron-produced radiopharmaceuticals and a PET centre. The main output will be radiopharmaceuticals based on short lived radionuclides which are safer for patients and more effective in detecting subtle changes in metabolism. Local sources will finance the installation and utilization of a low-cost cyclotron with high current output dedicated to the production of PET radioisotopes and associated visualization techniques. The overall plan involves the following sequence of activities. (1) Installation and startup of the production facility for cyclotron-produced medical radioisotopes and radiopharmaceuticals; (2) Installation and operation of three detection devices (two dual-head rotating 511 keV cameras and one triple-head rotating 511 keV camera) in other hospitals; (3) Establishment of a reliable manufacturer/distributor/customer system; (4) Installation and startup of a Nuclear Medicine Centre (with F-18 FDG investigation capacity of 10 patients per day); (5) Installation of other modules (the second and third F-18 FDG modules, O-15 water modules and N-13 ammonia modules); and (6) Application of additional pharmaceuticals (N-13 ammonia, C-11 acetate, and O-15 water). The project will focus at first on the production and commercialization of F-18 FDG. Further F-18 radiopharmaceuticals, and pharmaceuticals with ultra-short half life radionuclides will be produced at a later stage. Cardiac diagnostics will be the primary area of application.

NATIONAL COMMITMENT: The equipment and infrastructure is in place for the design, installation and operation of the production facility for cyclotron-produced positron-emitting radioisotopes and radiopharmaceuticals based on them. The national effort will emphasize regular production and daily distribution of radiopharmaceuticals to the PET centre at the Bulovka Hospital, Prague, and later to other hospitals. To meet its commitment, the Government: (1) has commenced the process of selecting the cyclotron and radiochemistry modules; (2) will install the first SPECT camera with high energy collimator at the General University Hospital in 1996 and, later, two additional SPECT cameras at the Thomayer Hospital and the Motol Hospital; and (3) will prepare in the Bulovka Hospital (about 1400 beds) the proposed production and utilization facility. The Government will execute the main project and will also provide the buildings for the equipment. The Nuclear Research Institute will provide all project personnel during construction and operation of the production and utilization facility. The Ministry of Health will be responsible for installing and operating cameras in the hospitals.

AGENCY INPUT: The Agency will co-ordinate international financial and technical support for the project, provide the equipment related to the production of F-18 and F-18 FDG; co-ordinate the provision of expert services; provide fellowships; and organize group activities.

PROJECT IMPACT: The establishment of a national PET centre will improve health care because it is a non-invasive method giving functional data on target organs perfusion and metabolism not available with computer tomography (CT) or nuclear magnetic resonance (NMR) imaging. Public health will benefit from allowing physicians to obtain rapid and correct diagnosis. In time, health care costs will decline. Czech pilot studies have shown that, as in other industrialized countries, the most frequent use of PET procedure is for heart diseases. The incidence of acute myocardial infarct is about 68,000 per year, of which approximately 28,000 patients are hospitalized. The construction of a PET centre will ensure the production, quality control and distribution of important medical radioisotopes. The Czech Republic has an advanced nuclear medicine community well prepared to make good use of these radiopharmaceuticals. Furthermore, the Nuclear Research Institute has extensive experience in cyclotron technology and radiopharmaceutical production. PET's effectiveness in identifying patients who might or might not benefit from surgery will reduce invasive procedures. This reduction will solve the problem of accessibility of coronary surgery for all appropriate and necessary cases. The cost of one PET scan has been estimated at about US $600. Since the fixed costs represent the main part of the total costs, the increased number of PET procedures performed per year will result in lowering the cost per scan. The cost benefit for 6000 PET studies per year is (a) total saving of over US $220,000 per year; and, (b) reduction of about 800 operations and 400 cardiac catheterizations per year. For full implementation of PET for cardiology assessment, the savings will be substantially higher, i.e. savings of nearly US $7.5 million and 3000 fewer operations. Reduced morbidity, mortality and complications are not included in these calculations, although these indirect savings can be even greater than calculated direct benefits. By the end of the project, the Czech Republic will have the full capability to transfer its experience in the establishment of such a PET centre to other Member States, especially to smaller countries in the region.